Applicant: Igawa et al. Serial No.: To Be Assigned

Filed: Herewith Page: 3 of 8

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

- 1. (Original) A solution wherein a high concentration of immunoglobulin is stabilized, and wherein the immunoglobulin is IgM.
- 2. (Original) The solution of claim 1, comprising IgM at a concentration higher than 1 mg/mL.
- 3. (Original) The solution of claim 1, which is an aqueous solution.
- 4. (Original) The solution of claim 1, which is a pharmaceutical formulation.
- 5. (Original) The solution of claim 1, comprising a polyvalent cationic ion.
- 6. (Original) The solution of claim 5, comprising the polyvalent cationic ion at a concentration of 1 mM to 1,000 mM.
- 7. (Currently Amended) The solution of claim 5, wherein the polyvalent cationic ion is a Mg magnesium ion or an Arg arginine ion.
- 8. (Original) The solution of claim 5, further comprising sugars.
- 9. (Original) The solution of claim 1, which is pH5 to pH8.

Applicant: Igawa et al.
Serial No.: To Be Assigned

Filed: Herewith Page: 4 of 8

10. (Original) The solution of claim 1, wherein the solution does not intrinsically comprise human-derived proteins other than IgM.

- 11. (Original) The solution of claim 1, wherein the solution does not intrinsically comprise proteins other than IgM.
- 12. (Currently Amended) A pharmaceutical formulation obtained by freezing or lyophilizing the solution of <u>claim 1</u> any one of claims 1 to 11.
- 13. (Original) A method for stabilizing a solution comprising a high concentration of immunoglobulin, wherein the immunoglobulin is IgM and wherein the method comprises adding a polyvalent cationic ion to the solution.
- 14. (Original) The method of claim 13, wherein the solution comprises IgM at a concentration higher than 1 mg/mL.
- 15. (Original) The method of claim 13, wherein the solution is an aqueous solution.
- 16. (Original) The method of claim 13, wherein the solution is a pharmaceutical formulation.
- 17. (Original) The method of claim 13, which comprises adding a polyvalent cationic ion to the solution such that the solution comprises the polyvalent cationic ion at a concentration of 1 mM to 1,000 mM.
- 18. (Currently Amended) The method of claim 13, wherein the polyvalent cationic ion is a Mg magnesium ion or an Arg arginine ion.
- 19. (Original) The method of claim 13, further comprising addition of sugars.

Applicant: Igawa et al.
Serial No.: To Be Assigned

Filed: Herewith Page: 5 of 8

20. (Original) The method of claim 13, wherein the pH of the solution is 5 to 8.

- 21. (Original) The method of claim 13, wherein the solution does not intrinsically comprise human-derived proteins other than IgM.
- 22. (Original) The method of claim 13, wherein the solution does not intrinsically comprise proteins other than IgM.
- 23. (Currently Amended) A method for stabilizing a pharmaceutical formulation, which comprises the steps of:
 - (a) performing the method of claim 13 any one of claims 13 to 22; and
 - (b) freezing or lyophilizing the solution stabilized in step (a).
- 24. (Original) A method for producing a solution comprising a high concentration of stabilized immunoglobulin, wherein the immunoglobulin is IgM and wherein the method comprises the step of adding a polyvalent cationic ion to the solution.
- 25. (Original) The method of claim 24, wherein the solution comprises IgM at a concentration higher than 1 mg/mL.
- 26. (Original) The method of claim 24, wherein the solution is an aqueous solution.
- 27. (Original) The method of claim 24, wherein the solution is a pharmaceutical formulation.
- 28. (Original) The method of claim 24, which comprises the step of adding a polyvalent cationic ion to the solution such that the solution comprises the polyvalent cationic ion at a concentration of 1 mM to 1000 mM.

Applicant: Igawa et al.
Serial No.: To Be Assigned

Filed: Herewith Page: 6 of 8

29. (Currently Amended) The method of claim 24, wherein the polyvalent cationic ion is a Mg magnesium ion or an Arg arginine ion.

- 30. (Original) The method of claim 24, which further comprises the step of adding sugars.
- 31. (Original) The method of claim 24, wherein the pH of the solution is 5 to 8.
- 32. (Original) The method of claim 24, wherein the solution essentially does not comprise human-derived proteins other than IgM.
- 33. (Original) The method of claim 24, wherein the solution essentially does not comprise proteins other than IgM.
- 34. (Currently Amended) A solution which is produced by the method of <u>claim 24</u> any one of <u>claims 24 to 33</u>.
- 35. (Currently Amended) A method for producing a pharmaceutical formulation, wherein the method comprises the steps of:
 - (a) performing the method of claim 24 any one of claims 24 to 33; and
 - (b) freezing or lyophilizing the solution produced in step (a).